

**COUNT V**

**ALLEGED MEDICAID FRAUD  
(Violations of NRS 422.540, *et seq.*)**

**CLAIM FOR COST RECOVERY AND CIVIL PENALTIES**

467. Answering for paragraph 467, repeats and incorporates as if fully set forth herein each and every response to the allegations in paragraphs 1 through 466.

468. Admits that Plaintiff purports to bring a claim for Medicaid cost recovery, but denies that Plaintiff may properly bring this lawsuit or obtain any relief against AstraZeneca under Count V.

469. Denies the allegations in paragraph 469, except admits that AZPLP is a manufacturer of drugs included in the Nevada Medicaid drug formulary, and otherwise denies knowledge or information sufficient to form a belief as to the other parties.

470. Admits that AstraZeneca has entered into a Rebate Agreement pursuant to 42 U.S.C. § 1396r-8, refers to 42 U.S.C. § 1396r-8, referenced in paragraph 470, for its content, which speaks for itself, and denies knowledge or information sufficient to form a belief as to the other parties.

471. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 471 as to the other parties, and, as to AstraZeneca, refers to 42 U.S.C. § 1396r-8, and to the Rebate Agreement referenced in paragraph 471, for their content, which speak for themselves.

472. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 472 as to the other parties, and, as to

AstraZeneca, admits that AstraZeneca complied with the requirements of 42 U.S.C. § 1396r-8.

473-475. Denies the allegations in paragraphs 473-475 to the extent they are directed at AstraZeneca, refers to the Court Order, dated June 10, 2004, which dismisses Plaintiff's "Best Price" claims for all AstraZeneca drugs except Zoladex, and otherwise denies knowledge or information sufficient to form a belief as to the other parties.

476. Denies the allegations in paragraph 476 to the extent they are directed at AstraZeneca, and otherwise denies knowledge or information sufficient to form a belief as to other parties.

477. States that paragraph 477 consists of conclusions of law to which no response is required, otherwise denies the allegations in paragraph 477 to they extent they are directed at AstraZeneca, refers to the Court Order, dated June 10, 2004, which dismisses Plaintiff's "Best Price" claims for all AstraZeneca drugs except Zoladex, and denies knowledge or information sufficient to form a belief as to other parties.

477a. Denies that Plaintiff is entitled to a judgment or any other relief requested in its prayer for relief, as stated in the unnumbered paragraph following paragraph 477 of the Amended Complaint.

**COUNT VI**

**ALLEGED PUNITIVE DAMAGES  
CLAIM BROUGHT ON BEHALF OF THE STATE OF NEVADA**

478. Answering for paragraph 478, repeats and incorporates as if fully set forth herein each and every response to the allegations in paragraphs 1 through 477.

479. Denies the allegations in paragraph 479 to the extent they are directed at AstraZeneca, and otherwise denies knowledge or information sufficient as to the other parties.

479a. Denies that Plaintiff is entitled to a judgment or any other relief requested in its prayer for relief, as stated in the unnumbered paragraph following paragraph 479 of the Amended Complaint.

**XII. DEMAND FOR JURY TRIAL**

AstraZeneca denies Plaintiff is entitled to a judgment or any other relief requested in the Prayer for Relief.

**DEFENSES**

Without assuming the burden of proof of such defenses that it would not otherwise have, AstraZeneca asserts the following defenses:

**First Defense**

Plaintiff fails to state a claim against AstraZeneca upon which relief may be granted.

**Second Defense**

Some or all of Plaintiff's claims are barred, in whole or in part, by the political question and separation of powers doctrines.

**Third Defense**

Plaintiff has not suffered, and will not suffer, any injury to a legally protected or cognizable interest by reason of the conduct of AstraZeneca as alleged in the Complaint.

**Fourth Defense**

To the extent Plaintiff or any of its citizens for whom it is seeking relief obtains recovery in any other case predicated on the same factual allegations, it is barred from seeking recovery against AstraZeneca based on the Complaint pursuant to the doctrines of res judicata and collateral estoppel and the prohibition on double recovery for the same injury.

**Fifth Defense**

Plaintiff's claims are barred, in whole or in part, by the First Amendment to the United States Constitution and the analogous provisions of the Constitution of the State of Nevada.

**Sixth Defense**

Plaintiff's claims are barred, in whole or in part, to the extent that Plaintiff or any of its citizens for whom it is seeking relief has released, settled, entered into an accord and satisfaction or otherwise compromised its claims.

**Seventh Defense**

Any and all actions taken by AstraZeneca with respect to any of the matters alleged in the Complaint were taken in good faith and in accordance with established industry practice.

**Eighth Defense**

Plaintiff's state law claims are preempted, in whole or in part, by federal law, including without limitation, the Federal Employment Retirement Income and Security Act of 1974, the Federal Medicare Act, and the Federal Medicaid Act, including all amendments to the same and all regulations promulgated thereunder.

**Ninth Defense**

Plaintiff's claims are preempted by the dormant Commerce Clause of the United States Constitution.

**Tenth Defense**

Plaintiff's claims against AstraZeneca are barred because AstraZeneca has complied with all applicable regulations of the federal and state governments.

**Eleventh Defense**

Plaintiff's claims against AstraZeneca are barred, in whole or in part, by the applicable statutes of limitations and repose, and by the doctrines of laches, estoppel and waiver.

**Twelfth Defense**

Plaintiff's claims are barred, in whole or in part, because they violate AstraZeneca's rights under the Due Process and *Ex Post Facto* clauses of the United States Constitution, as well as the Constitution of the State of Nevada, insofar as Plaintiff seeks to impose liability retroactively for conduct that was not actionable at the time it occurred.

**Thirteenth Defense**

AstraZeneca's statements or actions were not the proximate cause or cause in fact of any injury or alleged loss.

**Fourteenth Defense**

Plaintiff fails to state with particularity facts to support the fraud allegations, and fails to plead with particularity the fraudulent concealment and multi source medicine allegations against AstraZeneca contained in the Complaint.

**Fifteenth Defense**

Plaintiff has no standing or capacity to bring some or all of the claims raised in this suit, including but not limited to, Plaintiff's asserted status in *parens patriae* to recover Medicaid or Medicare expenditures or to seek injunctive relief.

**Sixteenth Defense**

Plaintiff fails to allege with particularity its civil conspiracy claims against AstraZeneca as required by FED. R. CIV. P. 9(b).

**Seventeenth Defense**

Plaintiff's claims against AstraZeneca are barred because AstraZeneca did not directly or indirectly conspire with any other entity or engage in any other conduct in violation of state or federal law.

**Eighteenth Defense**

Plaintiff's claims against AstraZeneca are barred, in whole or in part, because AstraZeneca did not make any false statements to Plaintiff or any of the citizens for whom Plaintiff is seeking relief. As to any statement asserted against AstraZeneca that Plaintiff alleges to be false or misleading, AstraZeneca had no

reasonable grounds to believe, and did not believe at the time such a statement was made, that the statement was false or misleading.

**Nineteenth Defense**

Plaintiff's claims against AstraZeneca are barred because AstraZeneca did not directly or indirectly engage in any conduct in violation of state or federal law.

**Twentieth Defense**

AstraZeneca denies that Plaintiff has valid consumer protection claims against AstraZeneca under Nevada state law. However, if such claims are found to exist, AstraZeneca pleads all available defenses under the applicable laws.

**Twenty-First Defense**

Any allegedly fraudulent statements or conduct of AstraZeneca did not directly or proximately cause the alleged injuries as required under state consumer protection laws of Nevada.

**Twenty-Second Defense**

AstraZeneca's conduct was not "deceptive" as required under Nevada consumer protection laws.

**Twenty-Third Defense**

To the extent that Plaintiff seeks equitable relief against AstraZeneca, Plaintiff is not entitled to such relief because there is an adequate remedy at law.

**Twenty-Fourth Defense**

Plaintiff did not rely on the allegedly fraudulent statements or conduct of AstraZeneca as required under the Nevada consumer protection laws.

**Twenty-Fifth Defense**

Any allegedly fraudulent statement or conduct of AstraZeneca was not consumer-oriented as required under the Nevada consumer protection laws.

**Twenty-Sixth Defense**

Plaintiff's claims against AstraZeneca for injunctive relief were mooted by the passage of the 2003 Medicare reform legislation.

**Twenty-Seventh Defense**

Some or all of Plaintiff's claims for injunctive relief against AstraZeneca are barred by the doctrines of *in pari delicto* and/or unclean hands.

**Twenty-Eighth Defense**

Some or all of Plaintiff's claims against AstraZeneca arise from Plaintiff's failure to follow its federal and state statutory and regulatory obligation to set reimbursement rates at Estimated Acquisition Cost.

**Twenty-Ninth Defense**

Plaintiff's claims against AstraZeneca are barred, in whole or in part, due to its failure to join indispensable parties.

**Thirtieth Defense**

Plaintiff's claims against AstraZeneca are barred, in whole or in part, because it suffered no damages as a result of the matters alleged in the Complaint.

**Thirty-First Defense**

Plaintiff's claims are barred, in whole or in part, because any injuries sustained by Plaintiff were the result of its own conduct or the intervening or superseding conduct of third parties.



**Thirty-Second Defense**

Plaintiff's claims against AstraZeneca for damages are barred, in whole or in part, because: (1) Plaintiff failed to mitigate its damages, and that failure to mitigate damages should proportionately reduce the recovery of such persons and the allocation of any fault, if any exists, attributable to AstraZeneca; (2) Plaintiff would be unjustly enriched if allowed to recover any portion of the damages alleged in the Complaint; (3) by the doctrine of consent and/or ratification to the extent that Plaintiff has received and paid for medicines manufactured, marketed and sold by AstraZeneca after the filing of Plaintiff's original Complaint; and (4) Plaintiff's claims are speculative and remote and because of the impossibility of ascertaining and allocating those alleged damages.

**Thirty-Third Defense**

AstraZeneca is entitled to a set-off – should any damages be awarded against it – for the entire amount of all damages or settlement amounts recovered by Plaintiff, with respect to the same alleged injuries.

**Thirty-Fourth Defense**

The applicable statutory ceilings on recoverable damages must limit any damages recovered by Plaintiff from AstraZeneca.

**Thirty-Fifth Defense**

Plaintiff fails to allege facts or a cause of action against AstraZeneca sufficient to support a claim for attorneys' fees, treble damages and/or legal fees.

**Thirty-Sixth Defense**

Plaintiff's punitive damages claims against AstraZeneca: (1) have no basis in law or fact; (2) are not recoverable because the allegations of the

Complaint are legally insufficient to support a claim for punitive damages against AstraZeneca; (3) cannot be sustained because laws regarding the standards for determining liability for and the amount of punitive damages fail to give AstraZeneca prior notice of the conduct for which punitive damages may be imposed and the severity of the penalty that may be imposed and are void for vagueness in violation of AstraZeneca's due process rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and the Constitution of the State of Nevada; (4) cannot be sustained because any award of punitive damages exceeding the limits authorized by the laws or other comparable laws would violate AstraZeneca's due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would be improper under the Constitution, common law and applicable state laws of Nevada; (5) cannot be sustained because an award of punitive damages in this case, combined with any prior, contemporaneous, or subsequent judgments against AstraZeneca for punitive damages arising from the design, development, manufacture, fabrication, distribution, supply, marketing, sale, or use of AstraZeneca's medicines, would constitute impermissible multiple punishments for the same wrong in violation of AstraZeneca's due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would constitute double jeopardy in violation of the Constitution, common law and statutory law of Nevada; (6) cannot be sustained because any award of punitive damages without the apportionment of the award separately and severally between or among the alleged joint tortfeasors,

as determined by the alleged percentage of the wrong committed by each alleged tortfeasor, would violate AstraZeneca's due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would be improper under the Constitution, common law and public policies of Nevada; and (7) cannot be sustained because any award of punitive damages, which are penal in nature, without according AstraZeneca the same protections that are accorded to all criminal defendants, including the protection against unreasonable searches and seizures, the privilege against self-incrimination, and the rights to confront adverse witnesses, a speedy trial, and the effective assistance of counsel, would violate AstraZeneca's rights guaranteed by the Fourth, Fifth, and Sixth Amendments as incorporated into the Fourteenth Amendment to the United States Constitution and would be improper under the Constitution, common law and public policies of Nevada.

#### **Thirty-Seventh Defense**

Plaintiff's claim for punitive damages against AstraZeneca cannot be sustained because an award of punitive damages by a jury that: (1) is not provided constitutionally adequate standards of sufficient clarity for determining the appropriate imposition of, and the appropriate size of, a punitive damages award; (2) is not adequately instructed on the limits of punitive damages imposed by the applicable principles of deterrence and punishment; (3) is not expressly prohibited from awarding punitive damages, or determining the amount of an award of punitive damages, in whole or in part, on the basis of invidiously discriminatory characteristics, including without limitation, the residence, wealth, and corporate status of AstraZeneca; (4) is permitted to award punitive damages

under a standard for determining liability for punitive damages that is vague and arbitrary and does not define with sufficient clarity the conduct or mental state that makes punitive damages permissible; (5) is not properly instructed regarding Plaintiff's burden of proof with respect to each and every element of a claim for punitive damages; and (6) is not subject to trial court and appellate judicial review for reasonableness and furtherance of legitimate purposes on the basis of constitutionally adequate and objective standards, would violate AstraZeneca's Due Process and Equal Protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution, and would be improper under the Constitution, common law and public policies of Nevada.

#### **Thirty-Eighth Defense**

Plaintiff's claim for punitive damages against AstraZeneca cannot be sustained because an award of punitive damages that is subject to no predetermined limit, such as a maximum multiple of compensatory damages or a maximum amount of punitive damages that may be imposed, would: (1) violate AstraZeneca's Due Process rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution; (2) violate AstraZeneca's right not to be subjected to an excessive award; and (3) be improper under the Constitution, common law and public policies of Nevada.

#### **Thirty-Ninth Defense**

Plaintiff's fraud-based claims and Plaintiff's claims of fraudulent concealment are barred because Plaintiff knew or should have known before the filing of the complaint that published AWP's do not represent actual averages of the prices at which providers or pharmacies are able to purchase drugs.

**Fortieth Defense**

AstraZeneca adopts by reference any additional applicable defense pled by any other defendant in the companion cases consolidated for discovery by this Court, not otherwise pled herein.

**Forty-First Defense**

Plaintiff's "Best Price" claims with respect to all AstraZeneca drugs other than Zoladex, as well as Plaintiff's "Best Price" claims relating to Zoladex in Count IV, are barred by the Court Order dated June 10, 2004.

**Forty-Second Defense**

AstraZeneca hereby gives notice that it intends to rely upon any other and additional defense that is now or may become available or appear during, or as a result of the discovery proceedings in this action and hereby reserves its right to amend its answer to assert such defense.

WHEREFORE, AstraZeneca prays that this Court:

1. Dismiss Nevada's Amended Complaint with prejudice and enter judgment in favor of AstraZeneca against Plaintiff;
2. Award AstraZeneca its costs and expenses; and

3. Grant such other and further relief for AstraZeneca as this Court deems just and proper.

July 12, 2004

/s/ Lucy Fowler

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### **CERTIFICATE OF SERVICE**

I certify that on July 12, 2004, a true and correct copy of the foregoing document was served upon all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by causing a copy to be sent to Verilaw Technologies for posting and notification.

/s/ Lucy Fowler

Lucy Fowler